AMENDMENTS TO THE SPECIFICATION

Amend paragraph [0007] as follows:

--Stems designed for biological ingrowth typically rely on the bone itself to grow into a specially prepared surface of the component, resulting in firmly anchoring the device within the medullary canal. A shortfall of this approach is that, in contrast to components that utilize cement fixation, surfaces designed for biological ingrowth do not provide for immediate fixation of the <u>stem</u> because it takes time for the bone to grow into the specially prepared surface. Press-fit stems precisely engineered to fit within a surgically prepared medullary canal may or may not have specially prepared surfaces and typically rely on an interference fit of some degree of the component within the medullary canal of the bone to achieve stable fixation. Some stem components incorporate sharp cutting flutes or ridges at or near the tip of the stem of the component which are designed to engage in the cortical bone and tend to lock the device in place. A problem with this approach is that once the flutes engage, the rotational alignment of the device is determined.--

Amend paragraph [0020] as follows:

--These and other objects are achieved in one embodiment by the incorporation of flutes or ridges in the mid-shaft portion of the stem which allows substantially more rotational and positional adjustment before final seating of the stem than traditional stems with flutes or ridges at or near the distal tip of the stem. The flutes or ridges in the mid-shaft portion act as the bone engaging feature. The mid shaft flutes or ridges will allow the stem to engage the bone of the medullary canal to ensure a well fixed component while allowing positioning flexibility that does not exist today in devices. The fluted or ridged mid-shaft portion of the stem can also be tapered resulting in a conical geometry of the stem. Adjustment of this taper angle in the mid-shaft portion can achieve increased or decreased rotational and positional adjustment by reducing or increasing the taper angle respectively. Adjustment of the taper angle also can alter the degree of fixation by obtaining greater purchase of bone with [[a]]<u>an</u> increased taper angle or reduced purchase of bone with a decreased taper angle. In cemented devices the bone engaging portion may be replaced by spacing elements to

ensure central positioning and alignment of the device within the cement mantle of the medullary canal.--

Amend paragraph [0022] as follows:

--In one embodiment the neck portion and stem portion may be formed integrally in that they are one piece. In another embodiment, the stem and neck portions are de-coupled resulting in two distinct ~~pieces. A~~pieces: a modular neck portion which may be combined with a modular stem portion to allow additional rotational alignment and positioning of the neck portion independent from and relative to the stem. This achieves additional variable positioning independent of that achieved after full insertion of the stem portion. The modular neck portion can be locked to the stem portion in one of several positions to achieve the desired amount of rotational alignment. Furthermore the coupling means between the neck portion and the stem portion provides a reproducible strength and geometry of assembly between the two portions; the coupling means only requires some minimum number and force of impaction blows to achieve full assembly, where full assembly is defined by seating of the neck portion to the stem portion. Provided the two portions are fully assembled, the resulting strength of assembly and the axial position of the neck portion relative to the stem portion are dependent on the design and manufacturing tolerances, and are not dependent on the magnitude of force applied during assembly.--

Amend paragraph [0024] as follows:

--In one embodiment, the system of the present invention may include a stem portion with a proximal end, a midshaft bearing at least one axially directed ridge, and a distal non-ridged shaft. The system may further include a head portion and a neck portion. In one embodiment, the head portion is dimensionally adapted to articulate with a surgically prepared joint socket, and the neck portion is dimensionally adapted for bearing the head portion into an anatomically correct relationship with the surgically prepared joint socket. In one embodiment, the neck portion is formed integrally with the stem portion. [[And]]In another embodiment, the neck portion is removably attachable to the stem portion and mates therewith. The system may include means for removing the stem portion from the

medullary canal of the bone and may include means for detaching the neck portion from the stem portion. The system may further include coupling means for securely attaching the neck portion to the stem portion. In one embodiment, the neck portion may include a male spigot dimensionally adapted for insertion into a female bore. In one embodiment, the male spigot is split distally with at least one axially oriented slot. The male spigot and the female bore may be substantially cylindrical. The male spigot and the female bore may be formed using cylindrical shapes with different diameters. In one embodiment, a preselected circumference of a proximal cylindrical shape is greater than a preselected circumference of a distal cylindrical shape. In one embodiment, the stem portion may include a flat platform that supports the neck portion. The neck portion may include a flat surface that rests upon the stem portion. In one embodiment, [[and]] the distal non-ridged shaft may be slotted with at least one axially oriented slot. In one embodiment, at least two axially oriented slots are present. These slots may meet to form an acute angle. In one embodiment, the point of the acute angle is contoured to decrease its acuity.--

Amend paragraph [0027] as follows:

--In one embodiment, the present invention provides for a stem component of a joint replacement system that includes a proximal end, a distal end and a shaft. In one embodiment, the distal end is dimensionally adapted for being seated within the medullary cavity of a long bone and is slotted with at least one axially oriented slot. In one embodiment, the present invention provides for a system for seating [[and]]<u>an</u> implantable joint prosthesis in a surgically prepared bone that includes a stem with a proximal end, a distal end, a midshaft, and a distal shaft. According to this embodiment, the distal end is dimensionally adapted for insertion into a medullary cavity of the bone and a distal end is slotted with at least one axially oriented slot. Furthermore, the midshaft bears at least one axially oriented ridge suitable for cutting into a cortical surface of the medullary cavity. Furthermore, the distal shaft is unridged. In this embodiment, when the stem is seated within the bone, the proximal end extrudes from the proximal part of the surgically prepared bone.--

Amend paragraph [0041] as follows:

--Fig. 10 provides a perspective view of an embodiment of the present invention, showing 2 slots in the distal stem. <u>Fig. 10A provides a transverse cross-section view taken at line 10A–10A in Fig. 10.</u>--

Amend paragraph [0053] as follows:

--While a minimum of two to as large as twelve discrete positions are obtainable, it is preferred to have three to six discrete positions of the neck portion (40). As shown in Fig. 7, primary positioning may be obtained by indexing the keyed portion (27) of the stem (10) to that of the receiving slot (45) of the neck (40). Final locking may be obtained by the male cylindrical spigot (44) of the neck portion (40) locking within the corresponding cylindrical bore (28) of the stem portion (10). This locking may be achieved by one or more zones of diametrical interference between the spigot and bore. The diametrical interference between the cylindrical spigot and the bore is critical to proper functioning of the device, and may be in the range of 0.0005" to 0.0030". In one embodiment, there may be a nominal diametrical interference of 0.0020" at the proximal end of the spigot and bore and a nominal diametrical interference of 0.0010" at the distal end of the spigot and bore. The zone of diametrical interference may be limited to a proximal band (46) of approximately 0.040" to provide increased rotational resistance of the neck within the stem means, while maintaining reasonable assembly forces by controlling the amount of interference, the length of the zone and the axial location of the zone. In one embodiment, both the spigot and bore may incorporate gradual tapers and/or rounds at the surfaces leading into the zones of diametrical interference so as to avoid plowing of one or more surfaces during assembly and thus ease assembly of the neck portion to the stem portion. The length of the cylindrical spigot (44) is not critical; it only requires a length adequate to ensure a suitable locking surface and adequate axial engagement. It has been determined that a length of approximately 0.8" is satisfactory, although lengths selected from a range extending from 0.25" to 2.0" may offer advantages. In an alternate embodiment, the bore (28) may have a diameter at the base of the bore ~~larger~~ <u>smaller</u> than the diameter at the ~~entry~~ <u>corresponding portion</u> of the ~~bore~~<u>spigot</u>, which allows for increased resistance to axial distraction of the neck portion

from the stem portion. This difference in diameter is in the range of 0 to .020", and may be achieved in a multitude of ways, including continuous straight or curved surfaces, or discontinuous (stepped) surfaces.--

Insert new paragraph [0058.1] after paragraph [0058]:

--Fig. 10A shows a transverse cross-sectional view of the embodiment of Fig. 10 taken at cut line 10A–10A and illustrates the "V slot" tine configuration described above. Two slots (13A) and (13B) are arranged so that they form an acute angle. The slots define three tines (9A), (9B), and (9C). When the stem is implanted in a femur, tine (9C) is oriented so that it is nearer the patient's midline than the other tines and is consequently called the medial tine. Tines (9A) and (9B) are further away from the midline and called lateral tines. When the stem is implanted in a right femur, tine (9A) is called the anterolateral tine, and tine (9B) is called the posterolateral tine, because tine (9A) sits anteriorly (forward) and tine (9B) sits posteriorly (rearward). When the stem is implanted in a left femur, the names are reversed. As shown in Figs. 10 and 10A, the slots may be oriented longitudinally along the stem and positioned symmetrically, relative to a plane bisecting the stem longitudinally. In this way, tines (9A) and (9B) are each defined by one slot, and the medial tine is defined by both slots. Also as shown in Figs. 10 and 10A, slot (13A) may be so positioned that the thinnest dimension of lateral tine (9A) is perpendicular to the plane defined by that slot. The same may be true for slot (13B).--

Amend paragraph [0060] as follows:

--Fig. [[11]]12 shows that the mid-shaft portion (17) of the stem portion (10) incorporates ridges (20) while the distal portion (12) of the stem is free of any hindrance to rotation of the device within the medullary canal. Both the mid shaft (17) and distal portion (12) of the stem are generally either cylindrical or conical in shape or a combination of both. The mid shaft portion may include longitudinal ridges with intervening flutes to aid in positioning of the stem and to provide increased rotational stability of the stem in the bone. The mid shaft portion blends into the relatively larger proximal portion (19) of the stem which is designed

to fill the larger bone canal proximally and tends to follow the bone contour of the canal being larger on the medial side (32) of the device.--

Amend paragraph [0062] as follows:

--The mid shaft portion taper angle (22) can be adjusted from no taper (cylindrical) as shown in Fig. 8 to taper angles up to 45 degrees. Preferably this taper angle (22) is in the range of zero degrees to five degrees. Spacing of the ridges can be adjusted to maximize or minimize amount of bone purchase desired and is determined by the number of ridges (20), the thickness (23) of the ridges (20) and the mid-shaft stem diameter. The number of ridges (20) can range from a minimum of one to a number sufficient to allow for adequate fixation of the stem within the canal being limited only by the thickness (23) of the ridge and diameter of the stem. The number of ridges (20) preferably ranges from three to twelve. The thickness (23) of the ridges ranges from .002" to .050" and is preferably .005" to .010". Typical stem diameters ~~typically~~ range from 8mm to 20mm and can go beyond this range for special situations.--